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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/011,167	10/05/1998	JOHANNES J. GEUZE	RILE.001.OOU	9536

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/03/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/011,167

Applicant(s)

GEUZE ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,6 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed 8-13-02 (Paper No. 31) is acknowledged and has been entered.

The examiner notes that said amendment states on page 4 that claims 2-4 and 6 have been deleted. However the Office has no record of said claims having been cancelled. Applicant is requested to clarify.

Claims 2-4, 6, and 13-17 are pending and under consideration.

In view of said amendment, the outstanding 112 second paragraph and the art rejections have been withdrawn. However, a new ground of rejection has been applied necessitated by amendment.

NEW GROUND OF REJECTION

Claim Objections

Claims 2-4 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The recitation in claim 2 of "The antigen presenting vesicle according to claim 13 wherein said major histocompatibility complex protein is derived from MHC class I or class II" does not further limit base claim 13 which recites "An antigen presenting vesicle ...comprising a major histocompatibility complex (MHC) Class I protein...".

The recitation in claim 3 of "the antigen presenting vesicle according to claim 13 further comprising at least partially processed antigens" does not further limit base claim 13 which recites "An antigen presenting vesicle comprising ...one or more at least partially processed antigens...".

The recitation in claim 4 of "The vesicle according to claim 3 wherein said at least partially processed antigens are presented in the context of MHC Class I proteins." does not further limit the base claim 13 which recites "An antigen presenting vesicle ...comprising a major histocompatibility complex (MHC) Class I protein and one or more at least partially processed antigens bound to said MHC Class I protein" because antigens bound to MHC Class I are presented in the context of class I proteins.

The recitation in claim 6 of "The antigen presenting vesicle according to claim 13, wherein said antigen presenting cell is derived from a B lymphocyte, a Langerhans cell, a macrophage or a dendritic cell" does not further limit base claim 13 which recites "An antigen presenting vesicle obtainable from a B lymphocyte".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "wherein said antigen presenting cell" in line 2. There is insufficient antecedent basis for this limitation in the base claim 13.

MAINTAINED REJECTIONS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MAINTAINED Claims 13, 2, 3, 4 and 6, and newly added claims 14-17, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigen presenting vesicle comprising a membrane and a MHC Class II protein wherein said antigen presenting vesicle is obtainable from an antigen presenting cell, does not reasonably provide enablement for an antigen presenting vesicle comprising a membrane and any MHC Class I protein, or any functional derivative or fragment thereof, wherein said antigen presenting vesicle is obtainable from any cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

With regard to claims 2-4 and 6, Applicant has stated that said claims have been deleted, though as discussed supra, there is no record of this. So until said claims are cancelled, the instant rejection of said claims is maintained.

With regard to newly amended claim 13 and newly added dependent claims 14-17, the rejection has been maintained in part. Applicant contends that the rejection has been avoided in part by amending claim 13, so that claims 13-17 recite a cell that is a B lymphocyte, and by deleting the phrase "or a functional derivative or fragment thereof". The examiner agrees that said amendments have removed part of the instant rejection with regard to enablement of any antigen presenting cell and with regard to any functional derivative or fragment of a MHC Class I protein.

However, the instant specification is still not enabling regarding how to make and use an antigen presenting vesicle obtainable from a B lymphocyte comprising a MHC Class I protein as recited in newly amended claim 13 and newly added claims 14-17. Applicant notes that the examiner has noted that the instant specification discloses in its examples an antigen presenting vesicle derived from B cells. The examiner further notes

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presently that the instant specification does not disclose that said antigen presenting vesicle derived from B cells actually comprises MHC Class I proteins, but only discloses that said vesicles comprise MHC Class II proteins. Applicant contends that lymphocytes such as a human B cell line used to generate vesicles in the present invention, generally express MHC Class I proteins, with which the examiner agrees. Applicant further contends that said Class I expression in B cells, in part explains the presence of Class I proteins on lymphocyte derived vesicles; however, the examiner can not find support for said contention in the instant specification. It is noted that Tse et al (Journal of Experimental Medicine (1984) 159(1):193-207) teaches that vesicles showing MHC class I molecules were not found in B cells, see entire article, including the Abstract). Therefore, it would require undue experimentation to predict which antigen presenting vesicles derived from B cells comprise a MHC Class I protein without further guidance from the specification, or without objective evidence that the B cell derived vesicles exemplified in the instant specification comprise MHC Class I proteins.

Therefore, though Applicant's arguments have been fully considered, they are not persuasive, and the rejection is maintained in part, essentially for the reasons of record.

MAINTAINED Claims 13, 2, 3, 4 and 6, and newly added claims 14-17, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Response to Arguments

Applicant traverses the rejection on the grounds that language of the claims was present in the PCT application from which the instant application follows. However Applicant does not address the aspect of the instant rejection which notes that the instant specification does not describe an antigen presenting vesicle obtainable from a B cell that comprises a MHC Class I protein. It is noted that the instant specification describes an antigen presenting vesicle obtainable from a B cell wherein said vesicle comprises a MHC Class II protein, but does not describe that said vesicle (or any vesicle) comprises MHC Class I protein. Therefore, though the specification describes an antigen presenting vesicle obtainable from a B cell, wherein said vesicle comprises a MHC Class II protein, one of skill would not know they were in possession of an antigen presenting vesicle obtainable from a B cell, wherein said vesicle comprises a MHC Class I protein, without further description from the instant specification.

Therefore, though Applicant's arguments have been fully considered, they are not persuasive, and the rejection is maintained, essentially for the reasons of record.

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Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

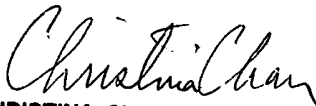
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
Art Unit 1644
November 23, 2002


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